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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/767,597	01/22/2001	Timothy J. Jegla	018512-002211US	2516

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TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
CHERNYSHEV, OLGA N	
ART UNIT	**PAPER NUMBER**
1646	6

DATE MAILED: 04/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/767,597	JEGLA, TIMOTHY J.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-21 and 24-39* is/are pending in the application.

4a) Of the above claim(s) *20,21 and 24-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I in Paper No. 5 is acknowledged. The traversal is on the ground(s) that "the all six groups set forth by the Examiner stem from a common concept and theory, and are thus related" (see the Response). This is not found persuasive because an application may properly be required to be restricted to one of two or more claimed inventions if they are able to support separate patents and they are either independent (MPEP § 806.04 - § 806.04 (j)) or distinct (MPEP § 806.05 - § 806.05 (i)). The Examiner has shown that the Groups are independent or distinct for the reasons in the previous Office action (see Paper No.4). Furthermore, MPEP § 803 provides that the separate classification (i.e., class and subclass) of distinct inventions is sufficient to establish a *prima facie* case that the search and examination of the plural inventions would impose a serious burden upon the Examiner; such separate classification was set forth in the Office action mailed February 13, 2002 (Paper No.4) Applicant has offered no evidence to rebut this showing. Therefore, a *prima facie* case for a serious search burden was presented in Paper No.4 and Applicant has offered no evidence to rebut this showing.

The requirement is still deemed proper and is therefore made FINAL.

Claims 20-21 and 24-39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 4.

Claims 13-19 are under examination in the instant office action.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 13-19 are rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility. The instant application has provided a description of an isolated nucleic acid encoding a polypeptide and the polypeptide encoded thereby. The instant application does not disclose the biological role of this polypeptide or its significance.

It is clear from the instant application that the polypeptide described therein is what is termed an "orphan protein" in the art. The nucleic acid of the instant application has been isolated because of its similarity to a known DNA. There is little doubt that, after complete characterization, this DNA and encoded protein may be found to have a specific and substantial credible utility. This further characterization, however, is part of the act of invention and until it has been undertaken, Applicant's claimed invention is incomplete. The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" as it appears in 35 U.S.C. § 101, which requires that an

invention must have either an immediate obvious or fully disclosed "real world" utility. The court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion".

The instant claims are drawn to a human HAC3 polypeptide of as yet undetermined function or biological significance. It is clear from the instant application that the protein described is structurally related to the voltage-gated cation channel family, specifically it is related to a family of hyperpolarization-activated channels (HAC). It is known from the literature, that these channels are involved in broad range of functions, rhythmic activity of the cells and changes in membrane potentials among them. Mouse HAC proteins have been identified and described before, and, according to the specification of the instant application "Isolation of human HAC3 is therefore desirable, to better understand the physiology of HAC3 in humans and for the development of therapeutic and diagnostic applications to diseases related to hHAC3 in humans" (page 3, lines 13-15 of the specification) (emphasis added by the Examiner). However, in the absence of knowledge of the biological significance of this specific polypeptide, there is no immediately obvious patentable use for it. According to the specification of the instant application "Modulators of hyperpolarization-activated channel activity may be useful for treating various pacemaker dysfunctions such as familial sinus rhythm diseases, sick sinus syndrome associated with atrial fibrillation, sinus tachycardias and bradycardias as well as

ventricular arryhythmias. The modulators are also useful for treating other disorders involving abnormal ion flux, e.g., memory and learning disorders, sleeping disorders, bipolar disease, schizophrenia, CNS disorders such as migraines, hearing and vision problems, seizures, and neuroprotective agents (e.g., to prevent stroke)" (page 9, lines 2-8). The similarity of the disclosed polypeptide to polypeptides associated with the diseases, disorders or conditions specified in the instant specification does not make the instant polypeptide diagnostic of these dysfunction, disorders or conditions. There is no evidence of record, which associates the instant polypeptide with any dysfunction or disorder. To employ the polypeptide of the instant invention in the future methods for treatment of these disorders and dysfunctions is not a real world because it would eventually relate to a protein for which no biological function is known. The instant application also fails to demonstrate use of the protein as a marker for any disease or condition (which would be a real world use). Because the instant specification does not teach a biological activity of the protein, one cannot prevent or treat a condition or disease as implied by the specification. To employ a polypeptide of the instant invention in any of the disclosed methods would clearly be using it as the object of further research which has been determined by the courts to be a utility which, alone, does not support patentability. Since the instant specification does not disclose a credible "real world" use for the claimed polypeptide then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 13-19 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a clear asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

4. Claims 13-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

It is noted that Claim 13 is directed to an isolated polypeptide having an amino acid sequence that has greater than 90% identity to amino acids 640-775 of SEQ ID NO:1, while SEQ ID NO:1 has only 774 amino acids. For the purpose of the examination it is assumed that fragment 640-775 is intended as 640-774.

Claims 13-19 are directed to isolated polypeptides which have amino acid sequences that have greater than 75% identity to amino acids 1-50 of SEQ ID NO:1 or greater than 90% identity to amino acids 640-774 of SEQ ID NO:1 or amino acid sequence that is greater than 90% identity to SEQ ID NO:1. However, the instant specification fails to describe the entire genus of proteins which are encompassed by these claims. In making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, it is necessary to understand what Applicant has possession of and what Applicant is claiming. From the specification, it is clear that Applicant has possession of an amino acid molecule of

SEQ ID NO:1. The subject matter, which is claimed is described above. First, a determination of the level of predictability in the art must be made in that whether the level of skill in the art leads to a predictability of structure; and/or whether teachings in the application or prior art lead to a predictability of structure. The claims are proteins having amino acid sequences that have greater than 75% identity to amino acids 1-50 of SEQ ID NO:1 or greater than 90% identity to amino acids 640-774 of SEQ ID NO:1 or amino acid sequence that is greater than 90% identity to SEQ ID NO:1. First, the claims are not limited to a protein with a specific amino acid sequence. The claims only require the polypeptide share some degree of structural similarity to the isolated protein of SEQ ID NO:1. The specification only describes a protein having the amino acid sequence of SEQ ID NO:1 and fails to teach or describe any other protein which lacks the amino acid sequence of SEQ ID NO:1 and has the activities possessed by the isolated protein. Therefore, there is a lack of guidance or teaching regarding structure and function because there is only a single example provided in the specification and because there is no guidance found in the prior art.

Next in making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, each claimed species and genus must be evaluated to determine whether there is sufficient written description to inform a skilled artisan that applicant was in possession of the claimed invention at the time the application was filed. With this regard, the instant application fails to provide a written description of the species or the genus which are encompassed by the instant claims except for the protein of SEQ ID NO:1. The specification does not provide a complete structure of those polypeptides which have amino acid sequences that have greater than 75% identity to amino acids 1-50 of SEQ ID NO:1

or greater than 90% identity to amino acids 640-774 of SEQ ID NO:1 or amino acid sequence that is greater than 90% identity to SEQ ID NO:1. The claims also fail to recite other relevant identifying characteristics (physical and/or chemical and/or functional characteristics coupled with a known or disclosed correlation between function and structure) sufficient to describe the claimed invention in such full, clear, concise and exact terms that a skilled artisan would recognize applicant was in possession of the claimed invention. The specification fails to provide a representative number of species for the claimed genus (those isolated polypeptides which have amino acid sequences that have greater than 75% identity to amino acids 1-50 of SEQ ID NO:1 or greater than 90% identity to amino acids 640-774 of SEQ ID NO:1 or amino acid sequence that is greater than 90% identity to SEQ ID NO:1) because the specification teaches only the one embodiment of SEQ ID NO:1. Therefore, the claims are directed subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 13 is indefinite for recitation of a fragment 640-775 of SEQ ID NO:1. According to the Sequence listing, SEQ ID NO:1 has 774 amino acids.

Conclusion

6. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 782-9306 for regular communications and (703) 782-9307 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)0. NOTE: If Applicant *does* submit a paper by fax, the original

signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D. OC
April 8, 2002

JOHN ULM
PRIMARY EXAMINER
GROUP 1800